Remarks

Claims 3-6, 8-15, 23, 25, and 31 have been amended to correct grammatical and typographical errors. Claim 25 has been amended to be an independent claim that includes all of the limitations of claim 15 from which it previously depended. Support for these amendments can be found in original claims 25 and 15 and in the specification at least at page 4, lines 17-27. Claims 26 -30, 32 and 33 have been amended to depend from claim 25.

Response to Restriction Requirement

In the Office Action mailed July 26, 2004, the claims were divided into five groups, Group I, claims 1-3, 6, 7, 13-29, 31, and 33, drawn to a method and devices of treatment that involve depositing drugs in the midzone of an organ; Group II, claims 1-5, 14-29, 31, and 32, drawn to a method and devices of treatment that involve depositing polymers in the midzone of an organ; Group III, claims 1-3, 8-11, 14-28, 30, and 31, drawn to a method and devices of treatment that involve depositing cells in the midzone of an organ; Group IV, claims 1-3, 11, 12, 14-28, and 31, drawn to a method and devices of treatment that involve depositing nucleic acids and vectors and host cells containing the nucleic acids in the midzone of an organ; and Group V, claims 1-3, 14-28, and 31 drawn to a method and devices of treatment that involve depositing diagnostic and therapeutic devices in the midzone of an organ.

In response, applicants elect Group I, claims 1-3, 6, 7, 13-29, 31, and 33, with traverse.

To be valid, a restriction requirement must establish both that (1) the "inventions" are either independent or distinct, and (2) that examination of more than one of the

"inventions" would constitute a burden to the Examiner. All of the allegedly separate inventions are clearly encompassed by independent claims 1, 15 and 25, as amended. The Examiner has even acknowledged that the pending claims are interrelated by making a restriction requirement between groups which he admits are connected by linking claims.

All of claims 1-33, as amended, are directed at methods, devices and kits for locally penetrating and entering the endomural zone of an organ, organ component, or tissue structure with minimal damage to the organ, organ component, or tissue structure to obtain access to endomural zones of an organ. The devices contain a hollow tubular member with (1) an end penetrating or cutting means and (2) a means for delivery of therapeutic agents. The kits contain these devices and a void filling material, which optionally contains a therapeutic agent.

In the restriction requirement, the Examiner focused on the purpose for the administration of different types of agents and their resulting therapeutic effects. However, these "results to be achieved" are not elements of the claimed methods, devices or kits. The result to be achieved does not affect the determination of the patentability of claims 1-33.

Contrary to the Examiner's assertion, different therapeutic agents do not require different steps. Thus, regardless of the type of therapeutic that is selected for deposition, the same steps will be involved, namely (1) locally penetrating and entering the body of an organ, organ component, or tissue structure and (2) depositing the drug or cell in the midzone, and the same device or kit will be used.

Finally, M.P.E.P. § 809 explains that "linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn. Any claim(s) directed to the nonelected invention(s), previously withdrawn from consideration, which depends from or includes all the limitations of the allowable linking claim must be rejoined and will be fully examined for patentability." (*Id.*) In this case, The Examiner has admitted that all of the groups are linked by claims 1, 2, 14-28, and 31. Thus, should linking claims 1, 2, 14-28, and 31 be found allowable, "the restriction requirement as to the linked inventions shall be withdrawn and any claims depending from or otherwise including all the limitations of the allowable linking claims will be entitled to examination." (Office Action dated July 26, 2004, page 4).

Favorable consideration of all of the claims, claims 1-33, as amended, is respectfully solicited.

Respectfully submitted,

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